K100795 Summary of S&E

We are **smith&nephew**

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	July 19, 2010
Contact Person and Address:	Shereen Myers, Regulatory Affairs Specialist T (901) 399-6325 F (901) 566-7075
Name of Device:	Smith & Nephew, Inc. Jet-X Bar System Clamps and Posts – Reprocessing
Common Name:	External Fixation Accessories
Device Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR 888.3030, Class II
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	KTT

SEP 0 2 2010

Device Description

Subject of this Traditional 510(k) premarket notification is the Reprocessed Jet-X Clamps. The subject reprocessed Jet-X clamps are specially designed components used in the management of bone fractures and reconstructive, as well as corrective, orthopedic surgery. The devices have been manufactured from stainless steel, aluminum and titanium alloys and have been designed to allow for the appropriate amount of rigidity and stability. Components of this premarket notification include:

- Freedom Clamp, Bar to Pin Clamps
- Freedom Clamp, Bar to Bar Clamps
- Freedom Clamp, Bar to Ring Clamps
- Mini Freedom Clamp, Bar to Pin Clamps
- Quick Clamp, Bar to Pin Clamps
- Mini Quick Clamp, Bar to Pin Clamps
- Pin Clamps, 4 and 6 holes
- Freedom Post
- Freedom Ankle Clamp
- Mini Double Pin Clamp with Ball Joint

These devices are used with existing components such as pins, wires, bars and other external fixation devices cleared in previous premarket notifications.

Technological Characteristics

A review of the mechanical data indicates that the Jet-X Bar System is capable of withstanding expected *in vivo* loading without failure, including after reprocessing. The following mechanical testing of the Jet-X clamps and posts was performed:

- Construct fatigue testing investigate reprocessing of the bar clamp
- Construct fatigue testing to investigate reprocessing of the bar to pin clamps
- Fatigue testing to investigate reprocessing of the bar to pin clamps
- Validation of steam sterilization process of Jet-X Bar System devices
- Validation for the refurbishment cleaning process of Jet-X Bar System devices

A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject devices. In addition, the principle of operation of these reprocessed devices very similar to that of the predicates. There are no changes in intended use, performance specifications or method of operation. The reprocessed devices utilize similar designs, the same materials and technological characteristics when compared to the predicate devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Intended Use

Jet-X External Fixation System components are intended to be used on adults or pediatric patients as required and are intended to be used for post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; open and closed fracture fixation; pseudoarthrosis of long bones; correction of bony or soft tissue deformities; correction of segmental bony or soft tissue defects; joint arthrodesis; infected fractures or nonunions; mini external fixator systems are indicated for the management of comminuted intra-articular fractures of the distal radius.

Substantial Equivalence Information

The substantial equivalence of the Jet-X Bar System Clamps and Posts for Reprocessing is based on its similarities in indications for use, design features, operational principles, and material composition to the following cleared premarket notifications:

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc	External Fixation Accessories	K031181	06/14/2003
Smith & Nephew, Inc	Jet-X Bar Clamps and Pin Clamps - Non-magnetic/MR Safe	K042312	09/24/2004
Smith & Nephew, Inc	Jet-X Bar System Clamps, Bars and Posts – MR Conditional	K072212	03/07/2008

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the Reprocessing of Jet-X Bar System Clamps and Posts. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to above predicate external fixation systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith and Nephew, Inc.
% Ms. Shereen Myers
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

SEP 0 2 2010

Re: K100795
Trade/Device Name: Jet-X Bar System Clamps and Posts - Reprocessing
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: August 25, 2010
Received: August 26, 2010

Dear Ms. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

SEP 0 2 2010

510(k) Number (if known): K100795

Device Name: Jet-X Bar System Clamps and Posts – Reprocessing

Indications for Use:

Jet-X External Fixation System components are intended to be used on adults or pediatric patients as required and are intended to be used for post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; open and closed fracture fixation; pseudoarthrosis of long bones; correction of bony or soft tissue deformities; correction of segmental bony or soft tissue defects; joint arthrodesis; infected fractures or nonunions; mini external fixator systems are indicated for the management of comminuted intra-articular fractures of the distal radius.

Prescription Use _X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler for JRF

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100795

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